

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT  
PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): June 8, 2023

**ORCHESTRA BIOMED HOLDINGS, INC.**  
(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction  
of incorporation)

001-39421  
(Commission  
File Number)

92-2038755  
(IRS Employer  
Identification No.)

150 Union Square Drive  
New Hope, Pennsylvania 18938  
(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: (215) 862-5797

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.0001 per share	OBIO	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 7.01. Regulation FD Disclosure.**

A copy of a slide presentation that Orchestra BioMed Holdings, Inc. (the "Company") uses at investor and industry conferences and presentations is attached to this Current Report on Form 8-K ("Current Report") as Exhibit 99.1 and is incorporated herein solely for purposes of this Item 7.01 disclosure. Additionally, the Company has posted the slide presentation on its website at <https://investors.orchestrabiomed.com> under the Investor Relations section.

The information in Item 7.01 of this Current Report, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of such section. The information in Item 7.01 of this Current Report, including Exhibit 99.1, shall not be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, regardless of any incorporation by reference language in any such filing.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

<b>Exhibit Number</b>	<b>Description</b>
<a href="#">99.1</a>	<a href="#">Investor Presentation.</a>
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**ORCHESTRA BIOMED HOLDINGS, INC.**

By: /s/ David Hochman  
Name: David P. Hochman  
Title: Chief Executive Officer

Date: June 8, 2023



# Orchestra BioMed

Corporate Presentation  
Q2 2023

Bringing medical innovation to life



# Forward-Looking Statements

This presentation has been prepared for informational purposes only from information supplied by Orchestra BioMed Holdings, Inc., referred to as “we,” “our,” “Orchestra BioMed,” and “the Company,” and from third-party sources indicated herein. Such third-party information has not been independently verified. Orchestra BioMed makes no representation or warranty, expressed or implied, as to the accuracy or completeness of the information.

Certain statements included in this document that are not historical facts are forward-looking statements for purposes of the safe harbor provided by the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements generally are accompanied by words such as “may,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “expect,” “should,” “would,” “plan,” “predict,” “potential,” “seem,” “seek,” “and similar expressions that predict or indicate future events or trends or that are not statements of historical matters. These forward-looking statements include, but are not limited to, statements relating to the potential safety and efficacy of our product candidates, the timing of our planned clinical development, expected market sizes for our product candidates, the ability of our partnerships to accelerate clinical development, and our estimated performance and financial position. These statements are based on various assumptions, whether or not identified in this document, and the expectations of the Company’s management and are not predictions of actual performance. These forward-looking statements are provided for informational purposes only and are not intended to serve as and must not be relied on as a guarantee, an assurance, a prediction, or a definitive statement of probability. Actual events and circumstances are difficult or impossible to predict and may differ from assumptions. Many actual events are beyond the control of the Company. These forward-looking statements are subject to a number of risks and uncertainties, including domestic and foreign business, market, financial, political, and legal conditions; failure to realize the anticipated benefits of the business related to regulatory approval of the Company’s product candidates; the timing of, and the Company’s ability to achieve expected regulatory milestones; the impact of competitive products and product candidates; and the risk factors discussed under the heading “Item 1A. Risk Factors” in the Company’s quarterly report on Form 10-Q filed with the U.S. Securities and Exchange Commission on May 12, 2023 as updated by any subsequent filings under the heading “Item 1A. Risk Factors” in the Company’s subsequently filed quarterly reports on Form 10-Q.

The Company operates in a very competitive and rapidly changing environment. New risks emerge from time to time. Given these risks and uncertainties, the Company cautions against placing undue reliance on these forward-looking statements, which only speak as of the date of this presentation. The Company does not plan and undertakes no obligation to update any of the forward-looking statements made herein, except as required by law.

# Orchestra BioMed Executive Summary



**Partnership-enabled business model** designed to **accelerate innovation** to patients, c  
partner and shareholder value and yield **exceptional future profitability**



**BackBeat CNT™** targets >\$10B  
annual hypertension markets  
*Firmware upgrade to existing  
pacemaker*

Statistically significant double-blind,  
randomized preliminary trial efficacy data  
*Plan to initiate pivotal trial H2 2023*

Strategic  
**Mec**  
Double-digi



**Virtue® SAB** targets >\$3B  
annual artery disease markets  
*Protected sirolimus delivery,  
non-coated balloon*

Strong 3-year multi-center preliminary trial  
safety and efficacy data  
*Plan to initiate pivotal trial H2 2023*

Strategic  
**TE**  
Double-digi



**Strong balance sheet and outstanding investors**

**Medtronic**



# Orchestra BioMed's Partnership-enabled Model Benefits All



## **Development**

Secure substantial long-term royalties  
Outsource commercialization  
Multiple pipeline opportunities

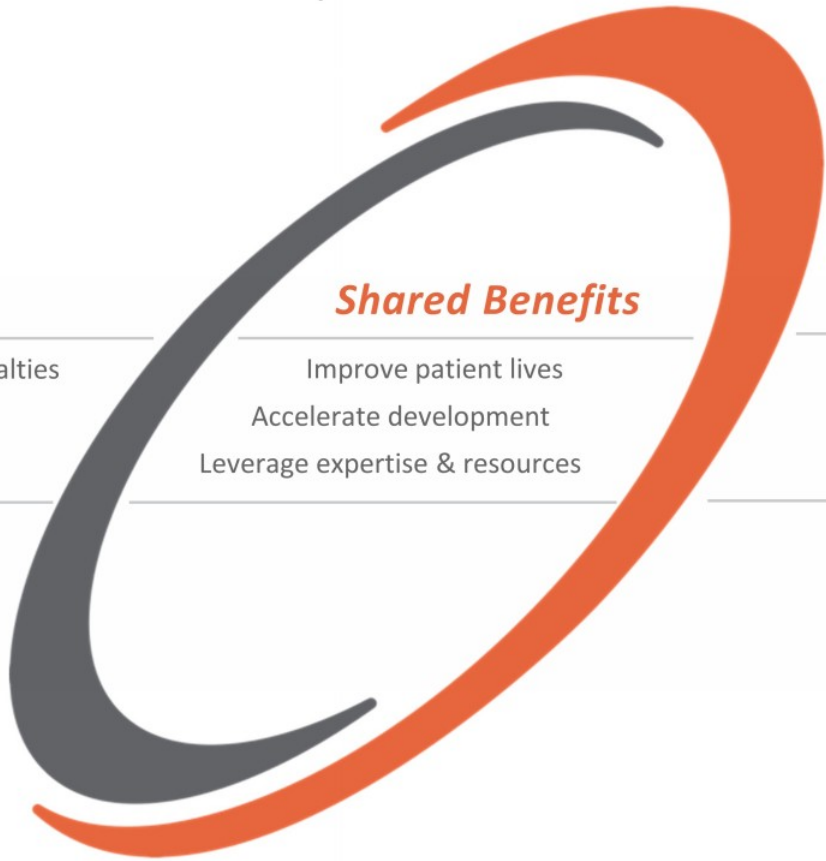
## **Shared Benefits**

Improve patient lives  
Accelerate development  
Leverage expertise & resources

## **Strateg**

### **Com**

Enable new grow  
Outsou  
Minir



# Highly Accomplished Executive Team & Board



**David Hochman**  
Chairman, CEO,  
Founder



**Darren R. Sherman**  
President, COO,  
Director, Founder



**Andrew Taylor**  
Chief Financial Officer



**Yuval Mika, Ph.D.**  
GM & CTO,  
Bioelectronic Therapies



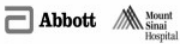
**George Papandreou, Ph.D.**  
GM & SVP,  
Focal Therapies



**Hans-Peter Stoll,  
M.D., Ph.D.**  
Chief Clinical Office



**Avi Fischer, M.D.**  
SVP, Medical Affairs  
& Innovation



**J.C. Simeon**  
SVP, Quality



**Inessa R. Wheeler**  
VP, Marketing



**Bob Laughner**  
VP, Regulatory Affairs



**Stephen A. Zielinski**  
VP, Product Dev.,  
Bioelectronic Therapies



**Ziv Belsky**  
VP, Research,  
Bioelectronic Therapies



**Executive Team: >250 Years of Experience, ~25 Avg Industry Years, >100 Product Approvals & >600 Aut**

**Jason Aryeh**  
Board Member



**Pamela Connealy**  
Board Member



**Eric S. Fain, M.D.**  
Board Member



**Eric A. Rose, M.D.**  
Board Member



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# Advancing High-Impact Pipeline

Product Platforms	Target Indications	Preclinical	Clinical Feasibility	Clinical Pivotal	Partners
BackBeat Cardiac Neuromodulation Therapy (CNT™)	Hypertension (HTN) (pacing patients; HTN+P)				Medtronic
	High-Risk HTN (non-pacing patients)				Medtronic ROFN
CNT - HF	Heart Failure				
Virtue® Sirolimus AngioInfusion™ Balloon (SAB)	Coronary In-Stent Restenosis (ISR)				TERUMO
	Coronary Small Vessel (SV) <sup>1</sup>				TERUMO
	Below-the-Knee (BTK) <sup>1</sup>				TERUMO
SirolimusEFR™ / Microporous Balloon	Urethral Strictures & BPH Osteoarthritis				

<sup>1</sup>Plan to leverage existing coronary ISR data to support potential Pivotal Study, although there have only been limited discussions with the FDA or a comparable foreign regulator in this regard. <sup>2</sup>Will seek to leverage data from HTN+P pilot and pivotal trials to support clinical and regulatory development for High-Risk HTN indication given that age and other demographic factors of the target population are expected to be similar, the type of hypertension treated will likely be isolated systolic hypertension which is predominant in the HTN+P population, and other co-morbidities are also expected to be common to both target populations. However, there have been no discussions with the FDA or a comparable foreign regulator in this regard. <sup>3</sup>Virtue SAB has received Breakthrough Device Designation for the balloon dilatation of the stenotic portion (up to 26 mm length) of a stented coronary artery (in-stent restenosis (ISR)) that is 2.25 to 4.0 mm in diameter, for the purpose of improving lumen diameter; <sup>4</sup>Virtue SAB has received Breakthrough Device Designation for the balloon dilatation of the stenotic portion (up to 26mm in lesion length) of a native coronary artery of 2.0 mm to 2.5 mm in diameter (small coronary arteries), for the purpose of improving lumen diameter; <sup>5</sup>Virtue SAB has received Breakthrough Device Designation for the balloon dilatation of the stenotic portion (up to 18 mm length) of an infrapopliteal artery (P-3 segment or distal, below the knee, with reference vessel diameter (RVD) 2.25 - 4.0 mm), for the purpose of improving lumen diameter. All references to clinical study initiations for HTN+P, Coronary ISR and Coronary SV indications are based on ongoing interactions with US FDA regarding IDE approvals or Japan PMDA regarding CTN approvals, which are required to start clinical studies. With respect to BackBeat CNT for HTN, Orchestra and Medtronic have had initial interactions with the FDA regarding IDE approval and expect to continue interactions regarding clinical trial design and submission requirements ahead of submitting documentation for approval in the second half of 2023. A pre-CTN discussion with the PMDA is planned for December 2022 with submission for CTN approval anticipated in the second half of 2023. With respect to Virtue SAB for Coronary ISR, Orchestra has been working on IDE approval with the FDA under the breakthrough designation program to define all of the elements necessary for IDE approval and Orchestra expects to complete the agreed upon work and submit documentation for approval in Q1 of 2023. Orchestra and Terumo have had initial interactions with the PMDA and expect to submit for CTN approval for Coronary ISR and SV studies in the second half of 2023. FDA and PMDA responses are expected approximately 30 days following formal submissions; clinical study enrollment is expected to begin approximately 6-8 weeks after regulatory approvals; study enrollment timelines are currently estimated to be 12-18 months for all referenced studies although actual study enrollment timeframes may be longer; final primary endpoint results for all studies are at 12 months from enrollment with the exception of Japan Coronary ISR & SV studies, which are expected to be at 6 months from enrollment.

# Strong Collaborations Position Us for Long-term Success

**BackBeat CNT**  
in collaboration with

**Medtronic**

## Medtronic

- Global market leader in pacemakers: **>\$1.5B** in annual revenues
- Providing leading device plus clinical & regulatory resources
- Exclusive global commercial rights for HTN+Pacemaker market
- **\$50M equity investment** in Orchestra BioMed
- Right of first negotiation to expand global rights for the treatment of non-pacemaker HTN patients

- Sponsor for BackBeat CNT HTN + Pacemaker global pivotal study
- **\$500 - \$1,600** per BackBeat CNT-enabled device sold<sup>1</sup> under existing reimbursement codes

**>\$10 Billion**

Targeted Annual Global Market Opportunities\*

**Virtue SAB**  
in collaboration with

**TERUMO**

## Terumo

- Global leader in interventional cardiology: **>\$2.5B**
- **\$30M upfront payment** and potential future milestones
- **\$5M equity investment** in Orchestra BioMed
- Responsible for clinical and regulatory expenses, US study, as well as device supply chain and commercialization
- Positioned to become Terumo's flagship therapeutic

- Sponsor for Virtue ISR-US pivotal study
- **10-15% royalty PLUS per unit payments** for Siroli
- Retains rights to Virtue SAB for clinical applications in coronary and vascular interventions

**>\$3 Billion**

Targeted Annual Global Market Opportunities\*

\*Total addressable market in 2025 based on company estimates; <sup>1</sup> Amount is based on higher of (1) a fixed dollar amount per device (amount varies materially on a country-by-country basis) or (2) a percentage of sales. <sup>2</sup> Based on Terumo's consolidated financial results for the fiscal year ended March 31, 2022

*BackBeat Cardiac  
Neuromodulation  
Therapy™ (CNT™)*



# BackBeat CNT™ Overview

## Unmet Need

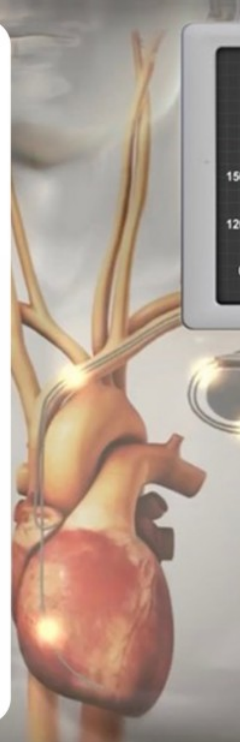
- **Hypertension is the leading global risk factor for death and #1 comorbidity in pacemaker population, affecting over 70% of patients<sup>1</sup>**
- Older population at **increased risk for major events** & challenges with drug compliance
- Additional opportunity to treat high-risk patients not indicated for a pacemaker

## Innovation

- Bioelectronic therapy **designed to substantially & persistently lower blood pressure**
- **Compatible with standard pacemaker devices** & leverages existing treatment paradigm
- **Compelling clinical data from double-blind randomized study:** significant 8.1 mmHg net reduction in 24-Hr aSBP at 6 months & 17.5 mmHg reduction in oSBP at 2 years<sup>2,3</sup>

## Collaboration with Medtronic

- **Global pacemaker leader** providing technology and support for global pivotal trial
- Exclusive commercialization rights in the pacemaker-indicated patient population
- **Orchestra Biomed to receive double-digit revenue sharing**

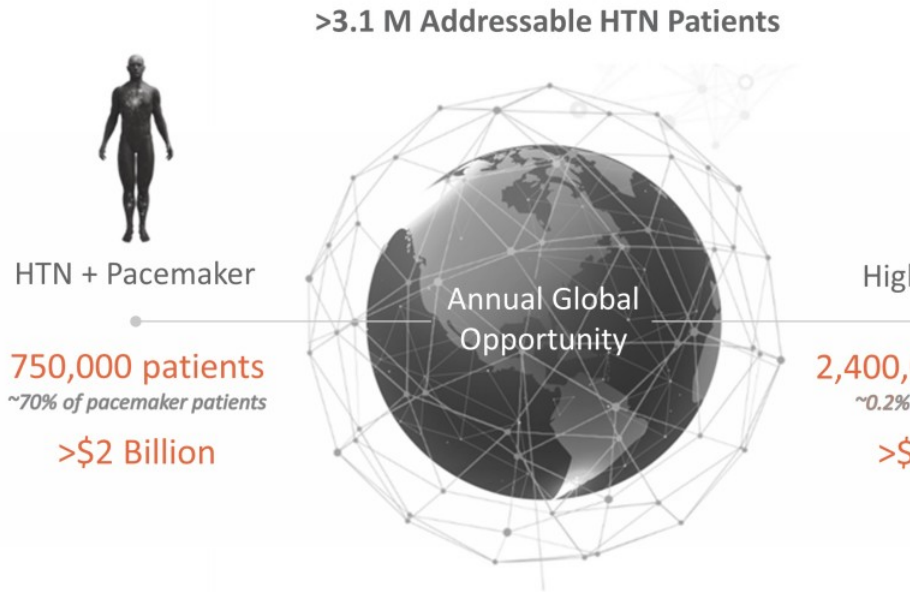


9 <sup>1</sup>Company estimates based on published sources, including National Inpatient Survey (NIS) and National Health and Nutrition Examination Survey (NHANES); <sup>2</sup>Kalaras et al. Journal of the American Heart Association. [ahajournals.org/doi/10.1161/JAHA.120.020492](https://doi.org/10.1161/JAHA.120.020492); <sup>3</sup>Burkhoff. MODERATO II Study 2-Year Results TCT 2021;. **Definitions:** Ambulatory Systolic Blood Pressure (aSBP) and Office Systolic Blood Pressure (oSBP)

# Large Global Opportunity for Treating Hypertension in Target Popula

**>\$10 Billion Potential Annual Global Market Opportunity\***

- HTN + Pacemaker**
- Over 70% of pacemaker patients have HTN<sup>1</sup>
  - Older, co-morbid population at increased risk of major events<sup>2</sup>
- High Risk HTN (Non-pacemaker)**
- Older patients with isolated systolic hypertension (ISH) and comorbidities



\*Total addressable market in 2025 based on company estimates; <sup>1</sup>Company estimates based on published sources, including National Inpatient Survey (NIS) and National Health and Nutrition Examination Survey (NHANES); <sup>2</sup>Known and well-characterized population, multiple references available; **Definition:** Hypertension (HTN)

# BackBeat CNT™

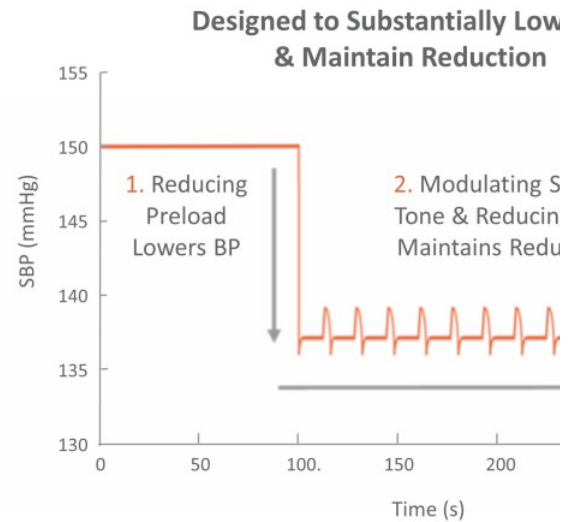
## *Designed to Substantially and Persistently Lower Blood Pressure*

- **Bioelectronic therapy designed to leverage standard dual-chamber pacemaker**

- Same implant procedure and lead positions
- Large trained physician pool that already implant pacemakers
- Same target patient population that already need pacemakers
- Leverageable existing reimbursement with robust payment opportunity for novel devices with novel capabilities

- **Mechanism of action**

- Designed to substantially reduce blood pressure by reducing preload through programmed pacing with short AV delays
- Designed to maintain reduction by modulating sympathetic tone and reducing afterload through programmed variable pressure patterns





# MODERATO II Double-Blind, Randomized Results

BackBeat CNT™ showed encouraging results in MODERATO II, a prospective, multi-center, randomized, (BackBeat CNT + Medical Therapy vs. Continued Medical Therapy), double-blind, pilot study of pacemaker patients with persistent hypertension

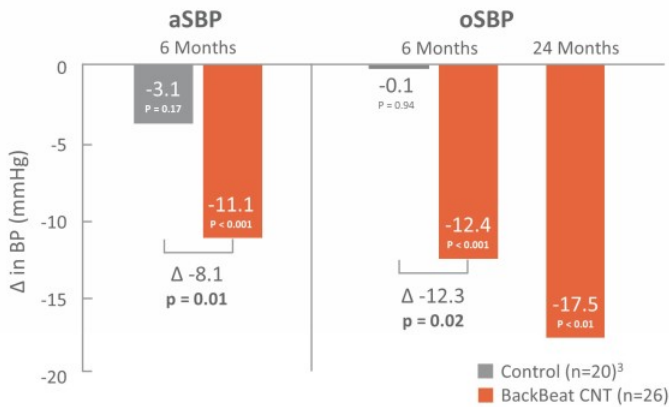
**-11.1 mmHg** in 24-Hour aSBP at 6 months

**-17.5 mmHg** in oSBP at 2 years

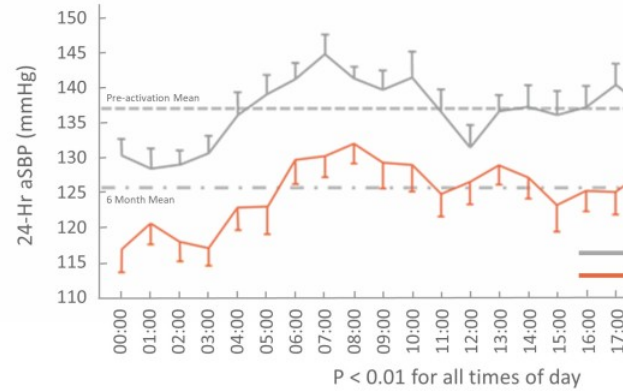
**0%** MACE vs. 9.5% in control group at 6 months

**85%** of patients with reduction in aSBP

## Significant Reduction in 24-Hr aSBP and oSBP<sup>1,2</sup>



## Significant Reduction in aSBP 24 Hour



<sup>1</sup>Kalaras et al. Journal of the American Heart Association. 2021;10:e020492 [ahajournals.org/doi/10.1161/JAHA.120.020492](https://doi.org/10.1161/JAHA.120.020492); <sup>2</sup>Burkhoff MODERATO II Study 2-Year Results TCT 2021; <sup>3</sup>24-Hr aSBP Control (n=19), 1 control patient could not be measured despite repeat measurement (patient had extremely high blood pressure); **Definitions:** Major Adverse Cardiac Events (MACE) included death, heart failure, clinically significant arrhythmias (i.e., persistent or increased atrial fibrillation, serious ventricular arrhythmias), myocardial infarction, stroke and renal failure in treatment group calculated per patient, Office Systolic Blood Pressure (oSBP), Ambulatory Systolic Blood Pressure (aSBP)

# BackBeat CNT™ Pivotal Trial Design

## ***Current anticipated trial design:***

- Prospective, multi-center, double-blind study investigating the efficacy of BackBeat CNT™ in patients with uncontrolled hypertension (HTN) despite the use of antihypertensive medications, who are in sinus rhythm and have a dual-chamber pacemaker
- Inclusion and exclusion criteria for enrollment in the BackBeat CNT Pivotal Study will be similar to the criteria used in the MODERATO II study
- Patients will be randomized 1:1 in a double-blinded manner to either active treatment with BackBeat CNT™ with continued antihypertensive medications or standard pacing only with continued antihypertensive medications
- Anticipated primary efficacy and safety endpoints:
  - ***Efficacy endpoint:*** Superiority of treatment as compared to control based on mean change in SBP at 2-3 months post randomization
  - ***Safety endpoint:*** Safety assessment will include evaluation of differences in composite cardiovascular events (CCAЕ) between groups at 12 months
- Enroll patients across ~80 study sites planned for United States, Europe and, potentially, Japan



*Virtue<sup>®</sup> Sirolimus  
AngioInfusion<sup>™</sup>  
Balloon (SAB)*



# Virtue<sup>®</sup> SAB Overview

## Unmet Need

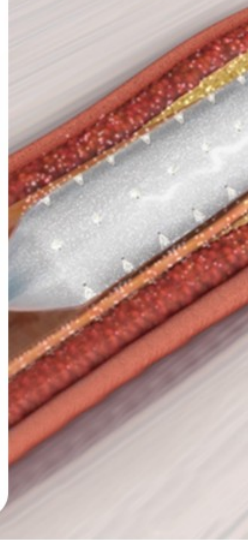
- Artery disease is the **leading cause of death** in the U.S. and worldwide
- **Significant paradigm shift toward “leave nothing behind”** treatment for coronary and peripheral indications representing an **>\$3B global market opportunity**<sup>1</sup>
- Current treatment options are suboptimal and are associated with long-term risks and complications

## Innovation

- **Highly-differentiated, non-coated drug/device combination** product candidate designed to reduce long-term complications by enabling angioplasty with protected delivery of extended release sirolimus
- **Compelling clinical results in multi-center coronary ISR clinical trial** with 3-year follow-up<sup>2</sup>
- **FDA Breakthrough Device Designation** received for indications in coronary ISR<sup>3</sup>, coronary SV<sup>4</sup> and BTK<sup>5</sup>

## Partnership with TERUMO

- **Global commercial leader** with >\$2.5B annual interventional cardiology revenue responsible for commercializing **Virtue SAB as flagship therapeutic offering**
- Collaboration driving multi-indication pivotal trial program starting with coronary ISR
- **Orchestra BioMed to receive double-digit royalties and per unit drug payments**

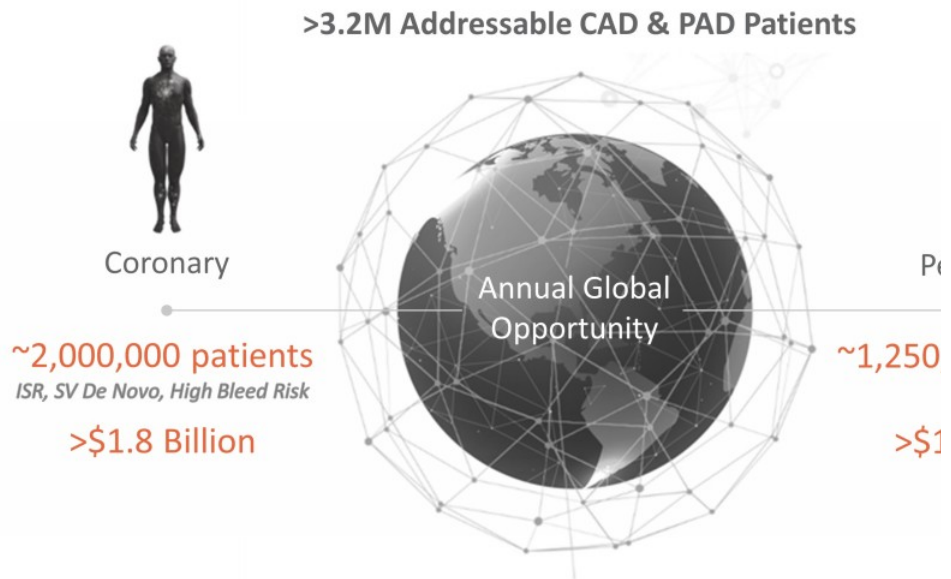


<sup>1</sup>Total addressable market is 2025 market data based on company estimates; <sup>2</sup>von Birgelen et al. JACC Vol. 59, No. 15, 2012 April 10, 2012:1350–61; Virtue SAB has received Breakthrough Device Designation for: <sup>3</sup>The balloon dilatation of the stenotic portion (up to 26 mm length) of a stented coronary artery (in-stent restenosis (ISR)) that is 2.25 to 4.0 mm in diameter, for the purpose of improving lumen diameter; <sup>4</sup>The balloon dilation of the de novo stenotic portion (up to 26mm in lesion length) of a native coronary artery of 2.0 mm to 2.5 mm in diameter (small coronary arteries), for the purpose of improving lumen diameter; <sup>5</sup>The balloon dilatation of the stenotic portion (up to 18 mm length) of an infrapopliteal artery (P-3 segment or distal, below the knee, with reference vessel diameter (RVD) 2.25 - 4.0 mm), for the purpose of improving lumen diameter.

# Large Opportunity for Leave Nothing Behind Solution

**>\$3 Billion Annual Global CAD & PAD Market Opportunity\***

- Artery disease is the primary cause of death worldwide
- Large mature market with significant unmet need
  - Suboptimal treatments for coronary ISR, coronary SV *de novo* and BTK
- Designed to leverage existing treatment paradigm & established technologies: sirolimus and balloon angioplasty



\*Total addressable market in 2025 based on company estimates; **Definitions:** Coronary Artery Disease (CAD), Peripheral Artery Disease (PAD), In-stent Restenosis (ISR), Small Vessel (SV, ≤2.5mm), High bleeding Risk De Novo (>2.5mm), Below-the-Knee (BTK, Rutherford 3-6, w/out severe comorbidities).

# Virtue<sup>®</sup> SAB

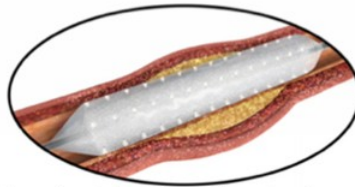
**Designed to Enable Angioplasty with Protected Sirolimus Delivery while Leaving No Metal Behind**

**AngioInfusion™ Balloon** designed to enable angioplasty with protected drug delivery to dilate vessel, to consistently deliver intended dose and to leave no metal behind



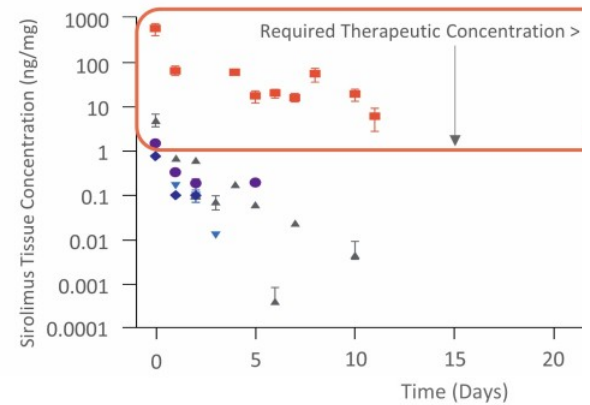
## Protected Delivery/No Drug Coating

- No drug loss in transit
- No time limits on delivery
- No drug coating particulates



Inflated to deliver dose through micropores

**SirolimusEFR™ Formulation** provided extended release of therapeutic levels of sirolimus throughout healing period ( $\approx 30$  days)<sup>1</sup>



N = 753 porcine coronary artery segments

Lung, liver & quantificatio

# Compelling SABRE Trial Results in Coronary ISR Patients

Virtue® SAB preliminarily demonstrated encouraging safety and efficacy results in patients with coronary in-stent restenosis (ISR) in prospective, multi-center SABRE Trial<sup>1</sup>

## Preliminary Efficacy Results Showed Low 0.12mm Late Loss

	Per Protocol <sup>4</sup>
n	36
Reference Vessel Diameter (RVD) mm <sup>1</sup>	2.52 ± 0.32
Minimum Lumen Diameter (MLD) mm	1.96 ± 0.32
% Diameter Stenosis	22.3 ± 9.4
Change in % Diameter Stenosis	5.2 ± 11.4
Late Lumen Loss (LLL) mm <sup>2</sup>	0.12 ± 0.33
Binary Restenosis <sup>3</sup>	2.8%

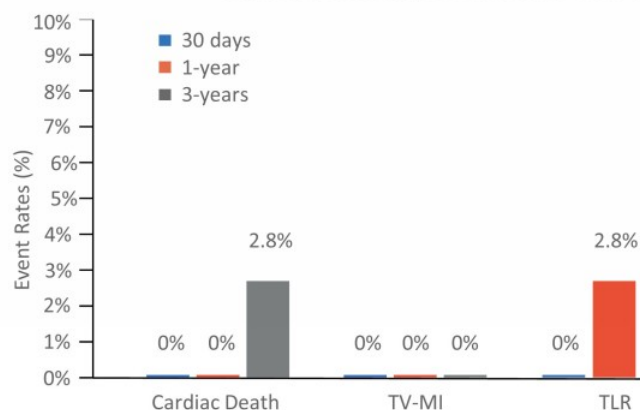
<sup>1</sup>RVD reported using Internormal values; <sup>2</sup>Trial primary performance endpoint; <sup>3</sup>Trial secondary performance endpoint (binary restenosis = >50% lumen diameter stenosis). <sup>4</sup>Data is based on per protocol population criteria revised to be consistent with proposed Virtue ISR-US pivotal study population.

0.12mm LLL at 6-months

2.8% Target Lesion Failure at 1 year

0% New TLR between 1 to 3 years

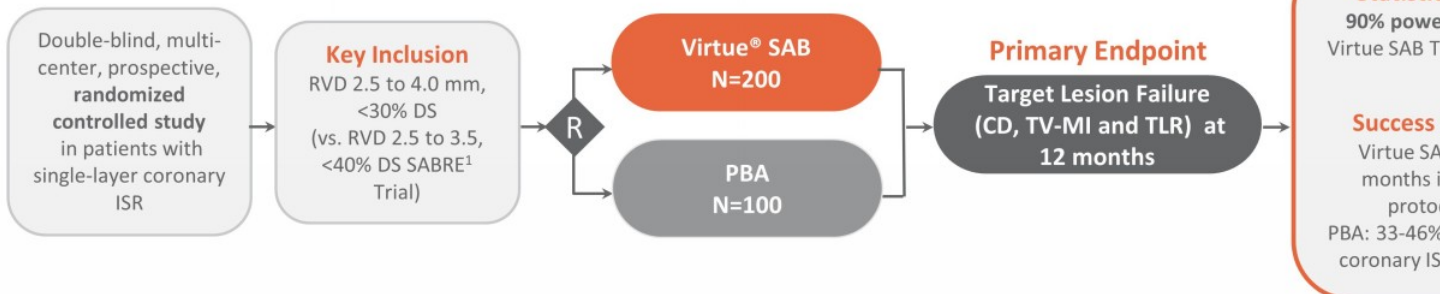
## Demonstrated Preliminary Safety with Low Safety Event Rates Out to 3 Years



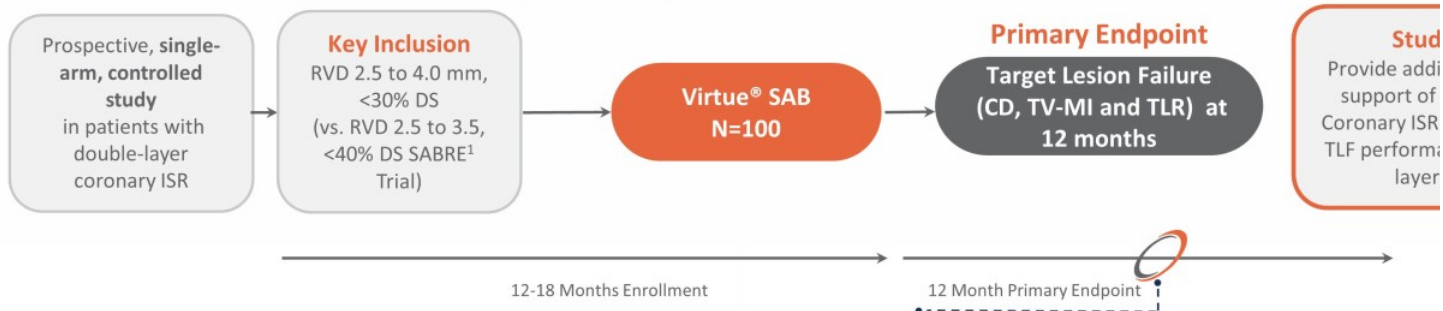


# Virtue<sup>®</sup> SAB Coronary ISR US Pivotal Trial

## Randomized Study Arm to Support Regulatory Approval: Single-Layer Coronary ISR



## Non-Randomized Study Arm: Double-Layer Coronary ISR



# 2023 - Anticipated Milestones



## Planned Regulatory Milestones

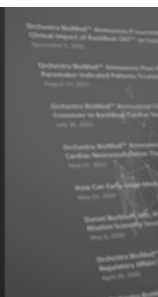
- BackBeat CNT
  - HTN + Pacemaker FDA IDE Approval
- Virtue SAB Coronary ISR
  - Virtue-ISR-US FDA IDE Approval
  - Japan PMDA CTN Approval<sup>1</sup>
- Virtue SAB – Coronary SV
  - Japan PMDA CTN Approval<sup>1</sup>



## Planned Clinical Milestones

- BackBeat CNT
  - HTN + P 1<sup>st</sup> Pt. Enrollment
- Virtue SAB
  - Coronary ISR 1st Pt. Enrollment
- CNT-HF and SirolimusEFR Prog Updates

# Bringing Medical Innovations to Life Through Partnerships



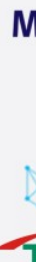
## **Partnership-Enabled Business Model & Accomplished Leadership Team**

- Designed to accelerate innovation to patients, enable pipeline expansion and drive strong partner and shareholder value
- Highly experienced team with proven track record of innovation and execution

## **Two Programs Targeting Large Markets Supported by Promising Trial Data Entering Pivotal Trials**

- **BackBeat CNT™**
  - >\$10 billion annual market
  - Randomized, controlled study shows efficacy potential
  - Collaboration with **Medtronic**
- **Virtue® SAB**
  - ~\$3 billion annual market
  - 3-year pilot study results show potential safety & efficacy
  - Partnered with **TERUMO**

## **Strong and Strategi**





# *Partnership-Enabled Business Model*



# Significant Barriers Prevent Innovation From Reaching Patient

Startups often **struggle for resources** to reach commercial value inflection

Avg \$60M funding needed, 85% of acquisitions required commercial traction<sup>1</sup>

Large companies' **constrained** innova

Avg 7% of revenue spent on R&D by top 20 med de



**Increasing burden of cost, time, and work**  
to bring medical innovation to patients

Product Development

Commercialization

# Orchestra BioMed Can Accelerate Innovation to Patients



*Risk-Reward Sharing **Partnerships**  
Can Overcome the Barriers to Innovation*



# Selecting Optimal Opportunities

## *Key Pipeline Criteria*

### **Large Market with Unmet Needs**

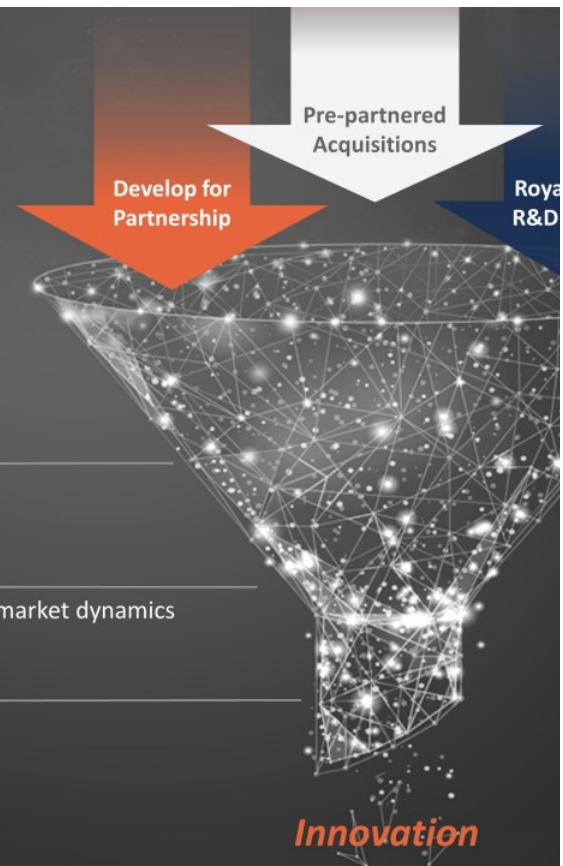
Large market, significant unmet needs, established distribution channels

### **Potential for High Impact**

Designed to improve standard of care, fit existing treatment paradigm, disrupt market dynamics

### **Favorable for Partnering**

Significant differentiation, attractive economics for partnership, durable IP protection





## Accomplished Leadership Team

*Created Pipeline, Pioneered Business Model and Established Partnerships*